

6-29-05

JC06 REC'D PCT/PTO 28 JUN 2005

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CERTIFICATE OF EXPRESS MAILING

I hereby certify that the foregoing Information Disclosure Statement and the accompanying Concise Statement of Relevance of Non-English References, Additional Information, Form PTO-144 (5 Sheets), 1 Search Report, and 6 references are being deposited with the United States Postal Service as express mail under label No. EV627049794US in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450, on the date indicated below:

JUN 28 2005 Date: June 28, 2005 By: *Olimpio Jakubernka Whitel*

Attorney Docket No.: 104599-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

|              |   |  |
|--------------|---|--|
| APPLICANT    | : | Goldstein, Naum et al.   |
| SERIAL NO.   | : | 10/527,941   |
| CUSTOMER NO. | : | 27,388   |
| FILED        | : | March 16, 2005   |
| FOR          | : | Pharmaceutical product for endonasal administration for treating central nervous system diseases and disorders |
| ART UNIT     | : | TBA  |
| EXAMINER     | : | TBA  |

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

SIR:

Pursuant to 37 CFR §§ 1.56, 1.97 and 1.98, Applicants respectfully request that the Examiner consider the references listed on the attached Form PTO-1449.

**I. Timeliness, Fees and Certifications in lieu of Fees**

A. This information disclosure statement is being filed within three months of the filing date of the application, or within three months of entry into the national stage, or before the mailing of a first Office Action on the merits. Pursuant to 37 CFR § 1.97(b), consideration of this information disclosure statement does not require a fee or a statement under 37 CFR § 1.97(e). However, should the Assistant Commissioner determine that a fee is, in fact, due, the Assistant Commissioner is hereby authorized to charge the fee to Deposit Account No. 14-1263.

B. This information disclosure statement is being filed after the period in A above, but before the mailing of either a final action or a notice of allowance. Pursuant to 37 CFR § 1.97(c), consideration of this information disclosure statement requires a fee or a statement under 37 CFR § 1.97(e):

1. The Assistant Commissioner is hereby authorized to charge the fee set forth in 37 CFR § 1.17(p) to Deposit Account No. 14-1263.

2. Applicants hereby state that each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

3. Applicants hereby state that no item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 CFR § 1.56 more than three months prior to the filing of this information disclosure statement.

C. This information disclosure statement is being filed after the period specified in B above, but on or before the payment of the issue fee. Pursuant to 37 CFR § 1.97(d), consideration of this information disclosure statement requires a petition, which Applicants hereby request, and payment of the petition fee, which is set forth in 37 CFR § 1.17(i), and which the Assistant Commissioner is hereby authorized to charge to Deposit Account No. 14-1263. Consideration of this information disclosure statement also requires a statement under 37 CFR § 1.97(e):

## II. Copies of Listed References

A. Copies of all references listed on the attached Form PTO-1449 are being supplied.

Copies of U.S. patents are not included pursuant to Pre-OG Notice dated July 11, 2003.

B. Copies of all references listed on the attached Form PTO-1449 have already been supplied during the prosecution of prior application Serial No. \_\_\_\_, filed \_\_\_\_, from which the present application claims priority pursuant to 35 USC § 120. Therefore, pursuant to 37 CFR § 1.98(d), copies of the references listed on the attached Form PTO-1449 are not now being supplied.

C. This application is a PCT national stage application, all references listed on the attached Form PTO-1449 were cited in the international search report, and PCT/DO/EO/903 indicates that both the international search report and the copies of the references listed on the attached Form PTO-1449 are in this national stage file. Therefore, copies of the references listed on the attached Form PTO-1449 are not now being supplied.

### **III. Concise Statement of Relevance**

A. All references listed on the attached Form PTO-1449 are in the English language, and, therefore, a concise statement of relevance is not required.

B. A concise statement of the relevance of all references listed on the attached Form PTO-1449 that are *not in the English language*, is being provided on a separate sheet.

C. All references listed on the attached Form PTO-1449 were cited in the search report issued by the \_\_\_\_\_ Patent Office, and an English-language version of that search report, which indicates the degree of relevance found by that Patent Office, is attached.

D. This application is a PCT national stage application, all references listed on the attached Form PTO-1449 were cited in the international search report, and a copy

of that search report, which indicates the degree of relevance found by the International Search Authority, is attached.

E. All listed on the attached Form PTO 1449 were cited during the prosecution of the prior application indicated above under II.B.

#### IV. Additional Information

A. In addition to the references listed on the attached Form PTO-1449, Applicants wish to bring to the attention of the Examiner the following abandoned or co-pending U.S. patent applications:

[Pursuant to 37 CFR § 1.98(a)(2)(iii), copies of these applications are not being submitted.]

B. In addition of the references listed on the attached Form PTO-1449, Applicants wish to bring to the attention of the Examiner the information provided on the attached sheet.

Consideration of the foregoing in relation to this application is respectfully requested.

Respectfully submitted,

NORRIS MC LAUGHLIN & MARCUS, P.A.

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|---|----------------------------------|----------------------------|
| <b>TYPE OF PATENTS AND PUBLICATIONS</b><br><b>APPLICANT'S INFORMATION</b><br><b>DISCLOSURE STATEMENT</b><br>(Form PTO-1449) | Attorney Docket: 104559-2        | Serial No.: To be assigned |
|   | Applicant: GOLDSTEIN, Naum et al | Examiner: To be assigned   |
|   | Filing Date: March 16, 2005      | Group: To be assigned      |

**U.S. PATENT DOCUMENTS**

| Examiner's Initial |    | Document Number    | Date       | Name          | Class | Sub Class | Filing Date If appropriate |
|--------------------|----|--------------------|------------|---------------|-------|-----------|----------------------------|
|                    | AA | US 6, 200591 B1    | 03/13/2001 | Hussain et al |       |           | 12/10/1998                 |
|                    | AB | US 2002/0022663 A1 | 02/21/2002 | Alfonso et al |       |           | 08/16/2001                 |
|                    | AC | US 5, 629,011      | 05/13/1997 | Illum et al   |       |           | 02/04/1993                 |

**FOREIGN PATENT DOCUMENTS**

|  |    | Document Number | Date       | Country | Class | Sub Class | Translation     |
|--|----|-----------------|------------|---------|-------|-----------|-----------------|
|  |    |                 |            |         |       |           | Yes No          |
|  | AD | WO9632120       | 10/17/1996 | World   |       |           | X abstract only |
|  | AE | DE19708643      | 08/27/1998 | Germany |       |           | X abstract only |
|  | AF | EP0967214       | 12/19/1999 | Europe  |       |           | X abstract only |

**OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)**

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**EXAMINER:**

**DATE CONSIDERED:**

- EXAMINER: Initial if Reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformation and not considered, include copy of this form with next communication to applicant.